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AU 200112628	A			A61K-009/48	Based on patent WO 200137817
BR 200015669	A			A61K-009/48	Based on patent WO 200137817
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SK 200200681	A3			A61K-009/48	Based on patent WO 200137817
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HU 200203299	B			A61K-009/48	Based on patent WO 200137817
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CN 1423554	A			A61K-009/48	

Abstract:

EP 1103254 A1

NOVELTY In the preparation of a starch-containing shaped article by (a) converting a mixture of starch, water and organic plasticizer into a homogeneous thermoplastic melt, by melting and kneading, (b) optionally preparing a storable intermediate product by cooling, then melting this product, (c) preparing at least one strand of the obtained material, (d) shaping into the article and (e) optionally drying, steps (a)-(c) are carried out such that the mass forming the strand in step (d) has a Staudinger index value of at least 40.

DETAILED DESCRIPTION Preparation of a starch-containing shaped article involves: (a) converting a mixture of starch (preferably at 45-80 wt. %), water and organic plasticizer(s) (I) into a homogeneous thermoplastic melt, by melting and kneading in a first apparatus, (b) optionally preparing a storable intermediate product (especially a granulate) by cooling, then melting this product in a second apparatus; (c) preparing at least one strand of material (preferably an extruded film) at the outlet of the first or second apparatus; (d) shaping the strand into an article in a continuous or intermittent forming process; and (e) optionally drying. The novel feature is that steps (a)-(c) are carried out such that the mass forming the strand in step (d) has a Staudinger index value of at least 40 (especially at least 60).

INDEPENDENT CLAIMS are included for:

(i) a homogenized mass containing (preferably at least 45 wt. % of) amorphous starch having an amylopectin content of at least 50 wt. % (based on anhydrous starch) and at least 12 wt. % (based on

anhydrous starch) of (I), having a Staudinger index value as above;

(ii) a shaped article formed by the above process and/or from a mass as in (i); and

(iii) apparatus for preparing a soft capsule from a mass as in (i) by the above process, where at least two film sheets are formed into a unitary capsule shell and provided with the capsule contents at a forming and filling station, the sheets being formed by an extruder located at this station and converted directly into the capsule.

USE The obtained articles are specifically soft capsules having a unitary capsule shell (claimed). Such capsules are especially gelatin-free capsules for drug administration (which have no risk of transmission of BSE via gelatin).

ADVANTAGE Readily weldable capsules having good transport and pressure stability are obtainable by a (semi-)continuous process, especially a rotary die process. The starch films for forming the capsule shell have an elongation at break of at least 100%. No leakage occurs from the capsules on storage for at least a year, the dissolution speed remaining unaffected. Capsule shells obtained by the process specifically have an elongation at break of at least 100% (specifically at least 240%) and a strength of at least 2 (specifically 3.5-8) MPa, both measured at 25degreesC and 60% relative humidity (all claimed).

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Technology Focus:

TECHNOLOGY FOCUS - POLYMERS - Preferred Materials: (I) is selected from polyols (especially glycerol), organic acids, hydroxyacids, amines, acid amides, sulfoxides and pyrrolidones; and is used at at least 12 (preferably 37-50, especially 38-45) wt. % based on anhydrous starch. The mixture in step (a) (or the claimed mass (i)) additionally contains at least one lubricant/mold release agent selected from lecithins, mono-, di- or triglycerides of edible fatty acids, polyglycerol, polyethylene or sugar esters of edible fatty acids and edible fatty acids; especially a mixture of glycerol monostearate and lecithin in weight ratio 1:1 is used. Mass (i) further contains 3.5-15 (preferably 5-8) wt. % filler(s) selected from alkali(ne earth) metal (bi)carbonates (especially calcium carbonate), amylases, further disintegration auxiliaries, dyes, preservatives, antioxidants, physically and/or chemically modified biopolymers and vegetable polypeptides.

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